DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-712

Schwarz Pharma, Inc.
Attention: Donna K. Multhauf
Director, Regulatory Affairs and Quality Assurance
P.O. Box 2038
6140 W. Executive Drive
Mequon, WI 53092 -4467

Dear Ms. Multhauf:

Please refer to your new drug application (NDA) dated November 24, 2003, received November 25, 2003, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fluxid™ (famotidine orally disintegrating tablets), 20 mg, 40 mg.

We acknowledge receipt of your submissions dated February 16, March 10, June 3, July 20, August 27, September 2, September 7, September 14, September 17, and September 22, 2004.

This new drug application provides for the use of Fluxid™ (famotidine orally disintegrating tablets) in adults for the following:

1. Short term treatment of active duodenal ulcer

2. Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of an active ulcer

3. Short term treatment of active benign gastric ulcer

4. Short term treatment of gastroesophageal reflux disease (GERD) and for the short term treatment of esophagitis due to GERD including erosive or ulcerative disease diagnosed by endoscopy

5. Treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison Syndrome, multiple endocrine adenomas)

and in pediatric patients for:

1. Short term treatment of gastroesophageal reflux disease (GERD) and for the short term treatment of esophagitis due to GERD including erosive or ulcerative disease diagnosed by endoscopy.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor agreed-upon editorial revisions submitted September 22, 2004 for your container labeling, professional sample label blister foil labeling, professional sample pack labeling, sample blister carton labeling, and professional sample display carton labeling. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted September 17, 2004) and submitted professional sample pack labeling submitted September 2, 2004.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

This submission should be designated "FPL for approved supplement NDA 21-712". Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectivenss of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug, Marketing, Advertising
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Betsy Scroggs, Pharm. D., Consumer Safety Officer at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

FLUXID™

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
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